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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,164	07/19/2001	Marguerita Lim-Wilby	IN01192	8821

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
AUDET, MAURY A	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,164	LIM-WILBY ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *20,22-28 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,21 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 & 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Change of Art Unit Designation

Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1648 to Art Unit 1654. To aid in matching papers in this application, all further correspondence regarding this application should be directed to **Group Art Unit 1654**.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-19, 21, and 29 as drawn to SEQ ID NO: 5, in Paper No. 4 is acknowledged. The traversal is on the ground(s) that "when there is a linking claim encompassing the scope of all the compounds, pharmaceutical compositions comprising them and methods of treatment using them, it is inappropriate to restrict the invention to a single compound" and that the search of all the claims would not cause an undue burden since the same search will most probably apply to the alleged inventions. This is not found persuasive because a search of the individual sequences and broad Formula I, necessarily constitutes a separate sequence or structure search thereto.

Notwithstanding the above, this Examiner reanalyzed the SEQ ID NOS: (47 in total) to find any distinguishable core structure, which may be searched without an undue burden. The following SEQ ID NO: groups were proposed (based in large part on the variation's of residue 8), as to the compounds of SEQ ID NOS: 1-52:

I. SEQ ID NOS: 5-13, and 42-47 (15), wherein residue 8, among other residue variations, is M.
II. SEQ ID NOS: 14-18 (5), wherein residue 8, among other residue variations, is G.
III. SEQ ID NOS: 19-27 (9), wherein residue 8, among other residue variations, is Q.
IV. SEQ ID NOS: 28-32 (5), wherein residue 8, among other residue variations, is T.
V. SEQ ID NOS: 33-41 (9), wherein residue 8, among other residue variations, is S.
VI. SEQ ID NOS: 48-49 (2), wherein residue 8, among other residue variations, is M (but L or nL at residue 6 instead of nV or V).

VII. SEQ ID NOS: 50-52 (3), wherein residue 8, among other residue variations, is M (but either Abu, or (s,s)alloT, or G(propynyl at residue 6, instead of nV or V).

As discussed with the Applicant's Attorney of Record on 6/9/03, elected SEQ ID NO: 5 was found to have at least a distinguishable enough core structure with SEQ ID NOS: 6-13, and 42-47, due to M at residue 8, and homology at residue 1-6, and 10-11. Applicant's Attorney responded by telephone on 6/11/03, and elected new Group I above, for examination on the merits.

Therefore, Group I, SEQ ID NOS: 5-13, and 42-47, as drawn to originally elected claims 1-19, 21, and 29, are examined on the merits. Claims 20, 22-28, and 30; as well as SEQ ID NOS: 14-41 and 48-52 are withdrawn from consideration.

The restriction requirement as to the non-elected claims and SEQ ID NOS: 14-41 and 48-52 is still deemed proper and is therefore made FINAL.

Rejections

35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19, 21, and 29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Namely, claim 1 is drawn to "a compound . . . with said compound having the general structure in Formula I." As claimed, the invention does not show the hand of man, and therefore reads upon a product found in nature. It is suggested that Applicant amend claim 1 to incorporate that the compound has been "isolated" or "purified".

35 U.S.C. § 112, 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19, 21, and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention, and claims 1-19, 21, and 29, are drawn to a compound and pharmaceutical composition of broad Formula I; namely, enantiomers, sterioisomers, rotomers and tautomers of said compound, and pharmaceutically acceptable salts, solvates or derivatives thereof, as well as specific SEQ ID NOS: 5-52.

One of skill in the art would not recognize from the disclosure that Applicant was in possession of the broadly claimed Formula I; namely, enantiomers, sterioisomers, rotomers and

tautomers of said compound, and pharmaceutically acceptable salts, solvates or derivatives thereof. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Namely, although the specification and claims describe SEQ ID NOS: 5-52; the same has not been shown of the enantiomers, sterioisomers, rotomers and tautomers of said compound, and pharmaceutically acceptable salts, solvates or derivatives, or any other SEQ ID NO: of broad Formula I.

Thus, neither the claims nor the specification details the amino acid sequences contemplated by the genus of Formula I other than SEQ ID NOS: 5-52. With the substantial variability among the broad genus Formula I; enantiomers, sterioisomers, rotomers and tautomers of said compound, and pharmaceutically acceptable salts, solvates or derivatives, or any other SEQ ID NO: of broad Formula I, it is not clear as to what such compound structures or functions are. One of skill in the art would not recognize from the disclosure that Applicant was in possession of the genus; namely enantiomers, sterioisomers, rotomers and tautomers of Formula I, and pharmaceutically acceptable salts, solvates or derivatives, or any other SEQ ID NO: thereof.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

35 U.S.C. § 112, 1st Scope of Enablement

Claims 1-19, 21, and 29 are ejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NOS: 1-52, does not reasonably provide enablement for any compound that reads on broad Formula I, namely enantiomers, sterioisomers, rotomers and tautomers of said compound, and pharmaceutically acceptable salts, solvates or

derivatives thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants have reasonably taught and/or demonstrated SEQ ID NOS: 1-52, as within broad Formula I. However, broad claim 1 necessarily encompasses any and all enantiomers, sterioisomers, rotomers and tautomers of said compound, and pharmaceutically acceptable salts, solvates or derivatives of broad Formula I. The SEQ ID NOS: are small peptides (11-mers), and it is well known in the art that even a slight change in the structure of a peptide, especially a small peptide, can drastically alter its native function. Factors such as stearic hindrance, change in polarity or conformation of the peptide leads to the change in the peptide structure and can affect its native function.

Based on the highly unpredictable and complex nature of peptide synthesis and function, determining which peptides could be made to correspond to the broad claim 1, namely as enantiomers, sterioisomers, rotomers and tautomers of said compound, and pharmaceutically acceptable salts, solvates or derivatives of Formula I would require undue experimentation without a reasonable expectation of success by one of skill in the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
June 12, 2003

MICHAEL MELLER
PRIMARY EXAMINER